K113601

TJOK

Summary of Safety and Effectiveness

NOV 8 2012

Sponsor:	***aap* Implantate AG** Lorenzweg 5 D-12099 Berlin Germany
Company Contact:	Dipl.-Ing. Marc Seegers Phone: +49-30-750-19 -192 Fax: +49-30-750-19 - 111
Date:	November 28, 2011
Trade Name:	*aap* LOQTEQ® Distal Medial Tibia Plate 3.5 System
Common Name:	Distal Medial Tibia Plate System
Classification:	
Classification Name and Reference:	21 CFR 888.3030 Single/multiple component metallic bone fixation appliances and accessories – Class II and 21 CFR 888.3040 Smooth or threaded metallic bone fixation fastener - Class II
Device Product Code and Panel Code:	Orthopedics/87/ HRS: Plate, Fixation, Bone Orthopedics/87/ HWC: Screw, Fixation, Bone
Predicate device:	3.5 LCP® Distal Medial Tibia Plates, Synthes (USA) premarket notification K013248 (DEC 19 2001)
Device Description:	Bone plates and screws are used for fixation of bone fragments, i.e., for treatment of bone fractures and other bone injuries. Bone plates are fixed by the use of bone screws. Bone plates and bone screws are implants. If the plates are used in conjunction with locking screws, a so called internal fixator (internal fixation) will be realized. The LOQTEQ® Distal Medial Tibia Plate 3.5 System consists of: • LOQTEQ® Distal Medial Tibia Plate 3.5, left and right version • LOQTEQ® Cortical Screws 3.5, self-tapping (locking bone screw) • LOQTEQ® Cortical Screws 3.5 small head, self-tapping (locking bone screw) • Cortical Screws 3.5, self-tapping • Cortical Screws 3.5 small head, self tapping • Instruments, Distal Medial Tibia Plate 3.5
Material:	Plates and Screws are made of titanium alloy Ti6Al4V according to ASTM F136 or ISO 5832-3.

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Indication:

The *aap* LOQTEQ® Distal Medial Tibia Plates 3.5 System is intended for

- Fixation of complex intra- and extra-articular fractures of the distal tibia
- Osteotomies of the distal tibia

Substantial Equivalence:

The Substantial Equivalence of the new device and the predicate device is based on similar intended use, design, functionality, components and materials in use.

Documentation including mechanical testing to show the substantial equivalence and safety and effectiveness has been provided with this submission.

Performance Data (Non-Clinical and/or Clinical):

Non-Clinical tests have been performed and show the effectiveness and safety of the device.

Summary of Non-clinical tests:

Type of test:
Fatigue implant tests with progressive loadings, representing worst case scenario with respect to clinical use.

Assessment of test results:
Substantial equivalence with respect to the mechanical performance of the aap system could be stated due to the test results gained. The subject device is safe and effective, and whose performance meets the requirements of its pre-defined acceptance criteria and intended uses.

Documentation regarding the mechanical testing to show the substantial equivalence and safety and effectiveness has been provided with this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

aap Implante AG
% Mr. Marc Seegers
Director QA/RA
Lorenzweig 5
D-12099 Berlin
Germany

Letter Dated: November 8, 2012

Re: K113601
Trade/Device Name: LOQTEQ® Distal Medial Tibia Plate 3.5 System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: October 19, 2012
Received: October 22, 2012

Dear Mr. Seegers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K113601

Device Name: LOQTEQ® Distal Medial Tibia Plate 3.5 System

Indications for Use:

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- Osteotomies of the distal tibia

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113601